Complete Summary

GUIDELINE TITLE

Adult diabetes clinical practice guidelines.

BIBLIOGRAPHIC SOURCE(S)

Care Management Institute, Kaiser Permanente. Adult diabetes clinical practice guidelines. Oakland (CA): Kaiser Permanente, Care Management Institute; 2004 Mar. 167 p. [119 references]

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Diabetes, including:

- Type 1 diabetes
- Type 2 diabetes
- Gestational diabetes

GUIDELINE CATEGORY

Management
Prevention
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine

Pharmacology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations (evidence-based and consensus) on the prevention, treatment, and management of diabetes

TARGET POPULATION

Adults with diabetes who are seen in outpatient office settings

These Guidelines are not intended for patients younger than 18 years of age

INTERVENTIONS AND PRACTICES CONSIDERED

1. Interventions to delay the onset of Type 2 diabetes
    - Lifestyle interventions (healthy eating; increased physical activity)
    - Drug therapy intervention (metformin; acarbose)
    - Combination therapy (lifestyle plus medication)
2. Postpartum follow-up of gestational diabetes mellitus to prevent future progression to type 2 diabetes
    - Lifestyle interventions (weight control; lifestyle advice; patient education on increased risk)
    - Drug therapy intervention
    - Combination therapy (lifestyle plus medication)
3. Screening for type 2 diabetes with fasting plasma glucose

    Note: Guideline developers considered but did not recommend glycosylated hemoglobin (HbA1c) as a routine screening test.

4. Management of hypertension in patients with diabetes
    - Diastolic and systolic blood pressure thresholds and targets
    - Monotherapy with: thiazide diuretics, angiotensin-converting enzyme (ACE) inhibitors
    - Combination therapy with beta blockers, thiazide diuretics, calcium-channel blockers, ACE inhibitors, angiotensin receptor blockers (ARB)
5. Drug therapy (ACE inhibitors) for microalbuminuria in normotensive patients with diabetes
6. Lipid management in patients with diabetes (statin therapy)

7. Drug therapy for the primary and secondary prevention of cardiovascular disease (CVD) events in patients with diabetes (ACE inhibitor therapy; aspirin; beta blocker therapy; multifactorial interventions)
8. Management of blood glucose with intensive glycemic control (metformin as first line glucose lowering drug; intensive HbA1c threshold and target)

   Note: Guideline developers considered but did not recommend insulin & sulphonylurea as first line glucose lowering drugs.

9. Monitoring microalbumin in patients with diabetes and documented microalbuminuria on ACE inhibitors using repeat measurement of microalbumin levels
10. Screening for retinopathy
11. Foot screening with monofilament test
12. Self monitoring of blood glucose

MAJOR OUTCOMES CONSIDERED

- Timing of onset and incidence of diabetes and diabetes complications
- Functional/health status
- Quality of life
- Rates of hospitalization
- Rates of office visits
- Development of or progression to glycosylated hemoglobin (HbA1c/GHb)
- Morbidity and mortality related to diabetes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The following tables document the approach taken to find review literature on each topic.

Intervention to Delay the Onset of Type 2 Diabetes

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Searches					
Cochrane	Diabetes or diabetic	Systematic reviews	8/1/03	22	0

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Searches					
Clinical Evidence (Volume 9, May 2003)	Diabetes	Systematic reviews and randomized controlled trials (RCTs)	8/1/03	6	0
PubMed	"Diabetes Mellitus"(Medical Subject Heading [MeSH])	Meta-analysis, All Adult: 19+ years, English, Human	2001–Aug 1, 2003	15	0
	"Diabetes Mellitus, Non-Insulin-Dependent/prevention and control"[MeSH]	Randomized Controlled Trial, All Adult: 19+ years English, Human	2001–Aug 5, 2003	21	2

Post Partum Follow Up of Gestational Diabetes Mellitus to Prevent Future Progression to Type 2 Diabetes

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
Cochrane	Diabetes or diabetic	Systematic reviews	8/1/03	22	0
Clinical Evidence (Volume 9, 2003)	Diabetes	Systematic reviews and RCTs	8/1/03	6	0
PubMed	"Diabetes Mellitus"[MESH]	Meta-analysis, All Adult: 19+	1965–5/1/01	27	0

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
		years, English, Human			
PubMed	"Diabetes Mellitus"[MESH]	Meta-analysis, All Adult: 19+ years, English, Human	2001-9/24/03	15	0
PubMed	"Follow-Up Studies"[MeSH] AND "Diabetes, Gestational"[MeSH]	Meta-analysis, All Adult: 19+ years, English, Human	1965–9/24/03	0	0
		Randomized Controlled Trial, All Adult: 19+ years English, Human	1965–9/24/03	2	0

Candidates for Screening for Type 2 Diabetes

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Searches					
Cochrane	Diabetes or diabetic	Systematic reviews	8/1/03	22	0
Clinical Evidence (Volume 9, May 2003)	Diabetes	Systematic reviews and RCTs	8/1/03	6	0

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Searches					
PubMed	"Diabetes Mellitus"[MeSH]	Meta-analysis, All Adult: 19+ years, English, Human	2001–Aug 1, 2003	15	0
	"Diabetes Mellitus, Non-Insulin-Dependent/prevention and control"[MeSH]	Randomized Controlled Trial, All Adult: 19+ years English, Human	2001–Aug 5, 2003	21	0

Management of Hypertension in Patients with Diabetes

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Searches					
Cochrane	Diabetes	Systematic reviews	1/02–2/03	6	0
Clinical Evidence (Volume 9, May 2003)	Cardiovascular (CV) disease in diabetes	Systematic reviews and RCTs	5/30/02	18	4
PubMed	"Diabetes Mellitus"[MeSH]	Meta-analysis, All Adult: 19+ years, English, Human	1965–5/2003	37	0
	(((((("Diabetes Mellitus"	Randomized	1/2001–	19	1

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Searches					
	[MESH]) AND (hypertension/drug therapy[MESH] OR hypertension/prevention and control[MESH])) AND ((("Angiotensin-Converting Enzyme Inhibitors/therapeutic use"[MESH] OR Hydrochlorothiazide/therapeutic use[MESH]) OR "Adrenergic beta-Antagonists/therapeutic use"[MESH]) OR "calcium channel blockers/therapeutic use"[MESH]))	Controlled Trial, All Adult: 19+ years English, Human	3/2003		
	("Hypertension"[MESH] AND (((((((("Adrenergic beta-Antagonists"[MESH] OR "angiotensin-converting enzyme inhibitors"[MESH]) OR "Adrenergic alpha-Antagonists"[MESH]) OR "calcium channel blockers"[MESH]) OR "Diuretics"[All Fields])	Randomized Controlled Trial, All Adult: 19+ years English, Human	1/2001–3/2003	239	2
	"Hypertension"[MeSH Terms] AND "stepped-care"[Text Word]	Meta-analysis, All Adult: 19+ years, English, Human	1965–5/2003	2	0
		Randomized Controlled Trial, Adult, English, Human	1965–5/23/03	34	0

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Evidence					
Cochrane	Diabetes	Systematic reviews	7/1/03	18	0
Clinical Evidence	Diabetes	Systematic reviews and RCTs	7/1/03	65	0
PubMed	"Diabetes Mellitus"[MeSH]	Meta-analysis, All Adult: 19+ years, English, Human	2001–July 1, 2003	14	0
	"Diabetic Nephropathies/drug therapy"[MeSH] AND "Albuminuria/drug therapy"[MeSH]	Randomized Controlled Trial, All Adult: 19+ years English, Human	2001–July 1, 2003	6	0

Lipid Management in Patients with Diabetes

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Searches					
Cochrane	Diabetes	Systematic reviews	1/02–2/03	6	0
Clinical Evidence (Volume 9, May 2003)	Diabetes	Systematic reviews and RCTs	7/16/03	65	1
PubMed	"Diabetes	Meta-	1965–	37	0

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Searches					
	Mellitus"[MeSH]	analysis, All Adult: 19+ years, English, Human	5/2003		
	"Diabetes Mellitus"[MeSH] AND "Hyperlipidemia"[MeSH]	Randomized Controlled Trial, All Adult: 19+ years English, Human	April 2002–July 15, 2003 (Update of Clinical Evidence, Issue 9, May 2003)	17	0

Drug Therapy for Primary and Secondary Prevention of Cardiovascular Events in the General Diabetes Population

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Searches					
Cochrane	Diabetes	Systematic reviews	5/22/03	49	0
Clinical Evidence (Volume 9, May 2003)	CV disease in diabetes	Systematic reviews and RCTs	5/22/03	24	0
PubMed	"Cardiovascular Diseases/prevention and control"[MeSH] AND "Diabetes Mellitus"[MeSH]	Meta-analysis, All Adult: 19+ years, English,	1/2001–5/22/2003	6	0

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Searches					
		Human			
		Randomized Controlled Trial, All Adult: 19+ years English, Human	1/2001–5/22/2003	39	1

Management of Blood Glucose

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Searches					
Cochrane	Diabetes	Systematic reviews	1/02–2/03	6	0
Clinical Evidence (Volume 9, May 2003)	CV disease in diabetes	Systematic reviews and RCTs	5/30/03	18	0
PubMed	"Diabetes Mellitus"[MeSH]	Meta-analysis, All Adult: 19+ years, English, Human	1965–5/2003	37	0
	((((("Diabetes Mellitus"[MESH] AND ("blood glucose/drug effects"[MESH] OR "Hemoglobin A,	Randomized Controlled Trial, All Adult: 19+ years	1/2001–3/2003	26	0

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Searches					
	Glycosylated"[MESH])) AND (((("metformin"[MeSH Terms] AND "insulin"[MeSH Terms]) OR ("metformin"[MeSH Terms] AND "Sulfonylurea Compounds"[MESH])) OR ("metformin"[MeSH Terms] AND pioglitazones[All Fields]))) AND Randomized Controlled Trial[ptyp]) AND English[Lang]) AND "adult"[MeSH Terms]) AND "human"[MeSH Terms])	English, Human			

Monitoring Microalbumin in Patients with Diabetes and Documented Microalbuminuria on ACE Inhibitors

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Evidence					
Cochrane	Diabetes	Systematic reviews	7/1/03	18	0
Clinical Evidence	Diabetes	Systematic reviews and RCTs	7/1/03	65	0
PubMed	"Diabetes	Meta-	2001–	14	0

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Evidence					
	Mellitus"[MeSH]	analysis, All Adult: 19+ years, English, Human	July 1, 2003		
	"Diabetic Nephropathies/drug therapy"[MeSH] AND "Albuminuria/drug therapy"[MeSH]	Randomized Controlled Trial, All Adult: 19+ years English, Human	2001–July 1, 2003	6	0

Screening for Retinopathy

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Evidence					
Cochrane	((Diabetes or diabetic) and retinopathy)	Systematic reviews	8/1/03	22	0
Clinical Evidence (Volume 9, May 2003)	Diabetes AND retinopathy	Systematic reviews and RCTs	8/1/03	6	0
PubMed	"Diabetes Mellitus"[MeSH]	Meta-analysis, All Adult: 19+ years, English, Human	1965–May 10, 2001	27	0
	"Mass	Randomized	2001–	1	0

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Evidence					
	Screening"[MeSH] AND "diabetic retinopathy"[MeSH]	Controlled Trial, All Adult: 19+ years English, Human	Aug 1, 2003		

Foot Screening

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Evidence					
Cochrane	((Diabetes or diabetic) and foot)	Systematic reviews	8/1/03	25	0
Clinical Evidence (Volume 9, May 2003)	Diabetes AND foot	Systematic reviews and RCTs	8/1/03	9	1
PubMed	"Diabetes Mellitus"[MeSH]	Meta-analysis, All Adult: 19+ years, English, Human	Aug 1, 2003	27	0
	"Mass Screening"[MeSH] AND "diabetic foot/diagnosis"[MeSH]	Randomized Controlled Trial, All Adult: 19+ years English, Human	2001–Aug 1, 2003	0	0

Diabetes Self-Management

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
Cochrane	Diabetes or diabetic	Systematic reviews	8/1/03	22	0
Clinical Evidence (Volume 9, May 2003)	Diabetes	Systematic reviews and RCTs	8/1/03	6	1
PubMed	"Diabetes Mellitus"[MeSH]	Meta-analysis, All Adult: 19+ years, English, Human	Aug 1, 2003	27	0
	"Diabetes Mellitus"[MESH] AND ("Self Care"[MESH] OR "Patient Participation"[MESH] OR "Patient Education"[MESH])	Meta-analysis, All Adult: 19+ years, English, Human	1965–9/4/03	10	1
		Randomized Controlled Trial, All Adult: 19+ years English, Human	1965–9/4/03	60	0
	"Diabetes Mellitus"[MESH] AND ("Self Care"[MESH] OR "Attitude to Health"[MESH])	Meta-analysis, All Adult: 19+ years, English, Human	1965–9/4/03	5	0
		Randomized Controlled Trial, All Adult: 19+ years	1965–9/4/03	43	0

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
		English, Human			

Self Monitoring of Blood Glucose

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Searches					
Cochrane	Diabetes	Systematic reviews	3/01/03	6	0
Clinical Evidence (Volume 9, May 2003)	CV disease in diabetes	Systematic reviews and RCTs	5/30/03	18	0
PubMed	"Diabetes Mellitus"[MeSH]	Meta-analysis, All Adult: 19+ years, English, Human	1965–5/2003	37	0
	(((((("diabetes mellitus"[MeSH Terms] OR Diabetes mellitus[Text Word]) AND ((("self care"[MeSH Terms] OR self-care[Text Word]) OR ("blood glucose self-monitoring"[MeSH Terms] OR blood glucose self-monitoring[Text Word])) OR ("patient compliance"[MeSH Terms] OR patient	Randomized Controlled Trial, All Adult: 19+ years English, Human	1/2001–3/2003	16	0

Database:	Terms:	Article Type and Limits:	Time Frame:	# Found:	# in Evidence Table (ET):
New Searches					
	compliance[Text Word])))) AND ((((("glucose"[MeSH Terms] OR glucose[Text Word]) AND (("blood"[Subheading] OR "blood"[MeSH Terms]) OR blood[Text Word])) AND levels[All Fields]) OR ("urinalysis"[MeSH Terms] OR urinalysis[Text Word]))))				
Health Technology Assessments	Diabetes	Systematic reviews	N/A	6	0

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Guidelines Project Management Team performed systematic reviews of the medical literature on each of the clinical questions identified by the workgroup.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

To review and update the Care Management Institute (CMI) Diabetes Guidelines released in March 2002, a multidisciplinary, interregional CMI Diabetes Guidelines Workgroup—including participants from primary care, endocrinology, pharmacy, nursing, and health education as well as evidence-based medicine experts—was convened. This group met in May 2003 to define the scope of the revision. Following systematic review of the literature, all of the recommendations and supporting evidence were reviewed by the Guidelines Workgroup in depth through a series of conference calls in November 2003, after which the guidelines were submitted to the Kaiser Permanente (KP) Interregional Guidelines Steering Group Quality Review Subcommittee.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations are classified as either "evidence-based" or "consensus."

- Evidence-based recommendations are based on the workgroup´s review of relevant well-designed studies.
- Consensus recommendations were created where evidence was inadequate and the workgroup felt that a recommendation was needed to guide clinicians.

COST ANALYSIS

- A cost/benefit analysis related to risk of gastrointestinal (GI) bleed due to aspirin in patients with diabetes demonstrated that the costs of complications, related to the adverse effects of GI bleed, exceeded benefit for patient with a 5-year coronary artery disease (CAD) risk of 4%.
- A cost/benefit analysis using generic pricing for metformin compared to conventional therapy revealed that the use of metformin was cost saving in overweight, middle-aged patients with type 2 diabetes.
- Cost/utility analysis of screening intervals cite that it may not be warranted to perform annual retinal screening on all patients without previously detected retinopathy with type 2 diabetes. Tailoring recommended intervals based on individual circumstances may be preferable.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Kaiser Permanente Interregional Guidelines Steering Group Quality Review Subcommittee reviewed and sponsored (approved) the guidelines on January 22, 2003.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendations are identified as either "evidence-based" or "consensus." For definitions of the levels of recommendations see the end of the "Major Recommendations" field.

I. Prevention of Diabetes

A. Intervention to Delay the Onset of Type 2 Diabetes

In patients with impaired glucose tolerance or impaired fasting glucose*, methods to promote healthy eating and increased physical activity, targeted to achieve a sustained weight loss (5 to 7%), delay the onset of diabetes and are strongly recommended as first line therapy.

If lifestyle therapy is ineffective, drug therapy with metformin (1st choice) or acarbose (2nd choice) is an option. (Evidence-Based, Interregional Guidelines Steering Group [IRGSG]-sponsored)

*Included studies define impaired glucose tolerance as a glucose of 140 to 199 post 75g glucose load. (Evidence-based) The American Diabetes Association (ADA) defines Impaired Fasting Glucose as fasting plasma glucose (FPG) levels ≥100 mg/dL (5.6 mmol/L) but <126 mg/dL (7.0 mmol/L). (Consensus)

B. Post-Partum Follow Up of Gestational Diabetes Mellitus (GDM) to Prevent Future Progression to Type 2 Diabetes

In women with GDM, long-term postpartum follow up including weight control and lifestyle advice is recommended to prevent future progression to type 2 diabetes. Patients with GDM should be educated on their higher risk of developing type 2 diabetes after delivery. (Consensus, IRGSG-sponsored)

II. Screening

A. Candidates for Screening for Type 2 Diabetes

- Screening for type 2 diabetes in patients with hyperlipidemia (low-density lipoprotein [LDL] >130) or hypertension (blood pressure ≥140/90 mmHg) is recommended regardless of age.
- There is insufficient evidence for screening patients with other risk factors**. Screening for these patients is optional.
- There is insufficient evidence to recommend an optimal screening interval. Regions are encouraged to set appropriate screening intervals.

(Consensus, IRGSG-sponsored)

B. **Risk factors are defined as a family history of type 2 diabetes in first- and second-degree relatives; belonging to a certain racial/ethnic group (Native Americans, African-Americans, Hispanic Americans, Asians/South Pacific Islanders); or body mass index (BMI) $\geq$25kg/m^2; or having signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, polycystic ovary syndrome)

B. Test to Screen for Impaired Glucose Tolerance

If a test for impaired glucose control is desired, a Fasting Plasma Glucose is the recommended test. Glycosylated hemoglobin (HbA1c) should not be used as a routine screening test. (Consensus, IRGSG-sponsored)

III. Pharmacological Management of Diabetes

A. Management of Hypertension in Patients with Diabetes

Threshold to Initiate Drug Therapy in Patients with Diabetes and Hypertension

Initiate antihypertensive therapy in patients with diabetes with a systolic blood pressure of $\geq$140 mmHg and/or diastolic $\geq$85 to 90 mmHg. (Evidence-Based: diastolic blood pressure; Consensus: systolic blood pressure, IRGSG-sponsored)

When blood pressure (BP) is more than 20/10 mmHg to 30/10 mmHg above goal, consideration should be given to initiating therapy with two drugs, either as a separate prescription or in fixed dose combinations.

Note: For patients with diabetes and hypertension, the target blood pressure should be $\leq$130/80 mmHg. (Consensus, IRGSG-sponsored)

Initial Treatment of Diabetes and Hypertension

The Care Management Institute (CMI) Diabetes Guidelines Workgroup recommends either a thiazide type diuretic or an angiotensin-converting enzyme inhibitor (ACE-I) as the preferred first line drug for the treatment of diabetes and hypertension in the absence of heart failure, known coronary heart disease, or microalbuminuria. (Consensus, IRGSG-sponsored)

Step Therapy in the Treatment of Diabetes and Hypertension

- For 2 drugs: When a 2nd drug is required for hypertension control, it should be either an ACE-I or a diuretic.
- For 3 drugs: If blood pressure is not controlled on a thiazide-type diuretic in addition to an ACE-I, then treatment with a thiazide-type diuretic, an ACE-I, AND a beta-blocker is recommended.

(Consensus, IRGSG-sponsored)

Drug therapy for Patients with Diabetes, Hypertension, and Microalbuminuria or Diabetic Nephropathy

If a person with diabetes, hypertension, and microalbuminuria (or albuminuria) is intolerant to an ACE inhibitor, then, in the absence of contraindications, it is recommended that an angiotensin receptor blocker (ARB) be substituted to prevent progression of renal disease. (Consensus, IRGSG-sponsored)

Target Blood Pressure for People with Diabetes and Hypertension

For patients with diabetes and hypertension, the target blood pressure should be $\leq$130/80 mmHg.

(Evidence-Based: diastolic blood pressure; Consensus: systolic blood pressure, IRGSG-sponsored)

B. Drug Therapy for Microalbuminuria in Normotensive Patients

ACE Inhibitors should be used in normotensive patients with diabetes and microalbuminuria (or albuminuria). (Consensus, IRGSG-sponsored)

C. Lipid Management in Patients with Diabetes

Statin Therapy: Age greater than or equal to 40 years to 80 years

In patients with diabetes age $\geq$40 to 80 years and total cholesterol (TC) >135, treatment with a moderate dose of a statin (for example, at least 40 mg lovastatin daily*) is recommended.

(Evidence-Based, IRGSG-sponsored)

However, in patients with diabetes who are at very low coronary artery disease (CAD) risk (no history of cardiovascular disease [CVD] and fewer than 2 cardiovascular risk factors**), treatment with lipid-lowering medication is optional. (Consensus, IRGSG-sponsored)

*Lower doses recommended for patients at high risk for rhabodmyolysis

**Total cholesterol >200 mg/dL, high-density lipoprotein (HDL)-cholesterol $\leq$35 mg/dL, hypertension, microalbuminuria, or current smoking

Statin Therapy: Age less than 40 years

In patients with diabetes under age 40 who have no known CAD and who have 2 or more cardiovascular (CV) risk factors**, treat with lipid lowering drug therapy. Alternatively, use the Kaiser Permanente (KP) treatment tables provided in the original guideline document to identify candidates for treatment with lipid-lowering drug therapy. (Consensus, IRGSG-sponsored)

> **Total cholesterol >200 mg/dL, high-density lipoprotein (HDL)-cholesterol ≤35 mg/dL, hypertension, microalbuminuria, or current smoking

For patients under age 40 with diabetes and established CAD, treatment with a statin is recommended. (Consensus, IRGSG-sponsored)

Statin Therapy: Age greater than 80 years

For patients over age 80 with diabetes and no established CAD, shared decision making regarding statin therapy is recommended. (Consensus, IRGSG-sponsored)

For patients over age 80 with diabetes and established atherosclerosis, treatment with a statin is recommended. (Consensus, IRGSG-sponsored)

LDL Goals for Patients with Diabetes and No CAD

Starting a moderate dose statin as the only goal (refer to statin therapy recommendation) is an option. However, using an LDL goal instead of starting a statin or as secondary to starting a statin is also acceptable.

If the region chooses to use an LDL goal, one of the following can be used:

Alternative #1: If an LDL goal is used, an LDL ≤130 mg/dL is recommended for people with diabetes who do not have established CAD.

(Evidence-based, IRGSG-sponsored)

Alternative #2: Some experts prefer a LDL target <100 as an option for people with diabetes who do NOT have established CAD.

(Evidence-based, IRGSG-sponsored)

Note: In some people, a target LDL may be difficult to achieve. In these cases, use clinical judgment to weigh the benefits and risks of intensifying drug therapy. (Consensus, IRGSG-sponsored)

LDL Goals for Patients with Diabetes and Established Coronary Artery Disease

An LDL <100 mg/dL is recommended for people with diabetes and established coronary artery disease. (Consensus, IRGSG-sponsored)

Note: In some people, an LDL <100 mg/dL may be difficult to achieve. In these cases, use clinical judgment to weight the benefits and risks of intensifying drug therapy. (Consensus, IRGSG-sponsored)

D. Drug Therapy for the Primary and Secondary Prevention of Cardiovascular Disease (CVD) Events in Patients with Diabetes

ACE Inhibitor Therapy for Primary and Secondary Prevention of CVD in Diabetes

ACE inhibitors should be prescribed to patients with diabetes age ≥55 years with one or more cardiovascular factors (total cholesterol >200 mg/dL, HDL-cholesterol ≤35 mg/dL, hypertension, microalbuminuria, or current smoking) or a history of CVD (CAD, stroke, or peripheral vascular disease). (Evidence-Based, IRGSG-sponsored)

Aspirin Therapy in Diabetes for Prevention of CVD in Diabetes

Patients with diabetes should be treated with at least 75 mg/day aspirin. (Evidence-Based, IRGSG-sponsored)

Given the adverse bleeding effects, aspirin is not recommended in patients with diabetes who are at low risk for CAD*. (Consensus, IRGSG-sponsored)

> *The CMI Diabetes Guidelines Workgroup defines low risk as a 10-year risk of a CAD event <10% (see risk assessment tool http://members.kaiserpermanente.org/kpweb/pdf/feature/247clinicalpracguide/KPSCal_DyslipidemiaGuideline_public_web_062503.pdf)

Beta Blocker Therapy for Secondary Prevention of CVD in Diabetes

Beta blockers are an option for secondary prevention of CVD in patients with diabetes. (Evidence-Based, IRGSG-sponsored)

Multifactorial Interventions for Preventing CVD in Patients with Diabetes

Concurrent treatment of CV risk factors is recommended for the prevention of CV events in patients with type 2 diabetes. (Consensus, IRGSG-sponsored)

E. Management of Glucose

Intensive glucose control is recommended in patients with diabetes, if not contraindicated.

(Evidence-Based, IRGSG-sponsored)

Metformin is recommended as the first-line glucose lowering drug in overweight patients with type 2 diabetes. (Evidence-Based, IRGSG-sponsored)

Assuming that normal HbA1c is <6% (adjust for regional normals), the treatment goal HbA1c is <7% and additional action should be taken if HbA1c is >8%. Patients with comorbid diseases, older adults, and patients with unusual conditions may need less stringent treatment goals. (Consensus, IRGSG-sponsored)

IV. Monitoring

A. Monitoring Microalbumin in Patients on ACE Inhibitors with Documented Microalbuminuria

Continued monitoring of microalbumin is optional in people with diabetes and established microalbuminuria who are on an ACE-I or ARB. (Consensus, IRGSG-sponsored)

B. Screening for Retinopathy

Diabetes patients with background retinopathy or more severe disease should be monitored at least annually, and those without retinopathy should be screened every 1 to 2 years. (Consensus, IRGSG-sponsored)

C. Foot Screening

All patients with diabetes should have a foot screening that includes a monofilament test. Patients with an abnormal monofilament test are at high risk for lower limb complications and are candidates for entry into a podiatry population-based foot care program, or equivalent. (Consensus, IRGSG-sponsored)

Annual foot screening is recommended for patients with diabetes. (Consensus, IRGSG-sponsored)

V. Self Management

A. Diabetes Self Management Education

Patient training in self-care behaviors is recommended as a component of any diabetes management program. (Evidence-Based: effect on glucose control; Consensus: effect on other outcomes, IRGSG-sponsored)

B. Self-Monitoring of Blood Glucose (Type 1 and Type 2 Diabetes)

Self monitoring of blood glucose is recommended for patients with type 1 diabetes and type 2 diabetes. When self-monitoring of blood glucose (SMBG) is used, results should be accompanied by an appropriate adjustment in therapy. (Evidence-Based: Type 1 Diabetes; Consensus: Type 2 Diabetes, IRGSG-sponsored)

Definitions:

Recommendations are classified as either "evidence-based" or "consensus."

- Evidence-based recommendations are based on the workgroup´s review of relevant well-designed studies.
- Consensus recommendations were created where evidence was inadequate and the workgroup felt that a recommendation was needed to guide clinicians.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall, this guideline is intended to help the clinician appropriately prevent, treat, and manage diabetes.

POTENTIAL HARMS

- Side effects of medications
- Anxiety, inconvenience, and possible inaccuracies associated with tests (microalbuminuria testing, retinopathy screening, foot screening)
- Decreased quality of life associated with self-monitoring of blood glucose

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines are informational only. They are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by practitioners, considering each patient´s needs on an individual basis.
- Guideline recommendations apply to populations of patients. Clinical judgment is necessary to design treatment plans for individual patients.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Care Management Institute, Kaiser Permanente. Adult diabetes clinical practice guidelines. Oakland (CA): Kaiser Permanente, Care Management Institute; 2004 Mar. 167 p. [119 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Mar

GUIDELINE DEVELOPER(S)

Kaiser Permanente Care Management Institute - Managed Care Organization

SOURCE(S) OF FUNDING

Kaiser Permanente Care Management Institute

GUIDELINE COMMITTEE

CMI Diabetes Guidelines Project Management Team

CMI Diabetes Guidelines Workgroup

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

No conflicts of interest by Management Team or Workgroup Members were noted.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available from the Kaiser Permanente Care Management Institute, One Kaiser Plaza, 16th Floor, Oakland, CA 94612.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 15, 2004. The information was verified by the guideline developer on September 16, 2004.

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Date Modified: 11/8/2004